DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

WARNING LETTER

DEC 20 2006

VIA FEDERAL EXPRESS

Robert W. Christensen, D.D.S.
President
TMJ Implants, Inc.
17301 W. Colfax Avenue
Suite 135
Golden, Colorado 80401

Dear Dr. Christensen:

On September 5, 2006, the Food and Drug Administration (FDA) obtained information from your Internet web site, http://www.tmj.com, that revealed you are promoting hemi and full mandibles without premarket clearance or approval from FDA.

According to your web site, TMJ Implants, Inc. "can design and deliver hemi and full mandibles to meet the most unique and unusual patient needs. These highly specific oral maxillofacial surgical (OMS) reconstruction solutions allow patients enhanced function and greater pain reduction." You further claim, for example, that:

- "TMJ Implants, Inc. has created solutions for such unusual conditions as Treacher-Collins and Goldenhar Syndromes"; and

- "Unusual cases involving trauma to the mandible and/or temporomandibular joint (TMJ), and disease states such as cancer or tumor have also been addressed."

Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), the hemi and full mandibles are devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body, 21 U.S.C. 321(h). A review of our records reveals that you have not obtained marketing approval or clearance before you began offering your products for sale, which is a violation of the law. We are aware that you have received marketing approval for the TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement System ™, which is intended for reconstruction of the TMJ due to one or more of the following conditions:

- Inflammatory arthritis involving the TMJ not responsive to other modalities of treatment

- Recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment
- Failed tissue graft
- Failed alloplastic joint reconstruction
- Loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion;

and for the Fossa-Eminence Prosthesis, which is intended for use to partially reconstruct the TMJ under the same conditions indicated for:

- the total joint replacement except for the last condition listed above and
- internal derangement confirmed to be pathological in origin by both clinical observation and radiographic findings, where the patient has moderate to severe pain and/or disabling dysfunction and has not responded to less invasive conventional therapy. You have not obtained approval for hemi and full mandibles that are intended for the uses described on your web site. You must obtain approval of either a new PMA or a supplement to one of your approved PMAs for these devices before they may be legally marketed.

The hemi and full mandibles are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. 360j(g). The devices are also misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency (21 CFR 807.81(b)).

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. In addition we request that you submit to our office distribution information for these devices for the past two years. If you need more time, let us know why and when you expect to complete your correction. Please direct your response or any questions you may have to:

Mr. Ronald L. Swann
Chief
Dental, Ear, Nose Throat, and
Ophthalmic Devices Branch (HFZ-331)
Division of Enforcement A
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850
U.S.A.

If you have any questions about the content of this letter please contact Mr. Swann by phone at 240-276-0115 or by fax at 240-276-0114.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of devices. This letter pertains only to the issue of premarket review for your device and does not necessarily address other obligations you have under the law.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health